

Application No. 10/526,285  
Amendment dated October 13, 2006  
Response to Office Action dated June 16, 2006

This listing of claims will replace all prior versions, and listing, of claims in the application.

**Listing of Claims:**

1. **(Currently Amended)** A pharmaceutical composition comprising metaxalone in a pharmaceutically acceptable solubility-improved form and at least one pharmaceutically acceptable excipient, characterized in that the pharmaceutical composition has enhanced oral bioavailability as compared to the conventional pharmaceutical composition of metaxalone available commercially corresponding to New Drug Application No. 13-217 when they are administered without food to a patient who has fasted on an empty stomach
2. **(Cancelled)**
3. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is micronized metaxalone.
4. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is a salt form of metaxalone.
5. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is a crystalline form of metaxalone.
6. **(Currently Amended)** A pharmaceutical composition as claimed in claim 2 1, wherein the solubility-improved form is amorphous metaxalone.
7. **(Original)** A pharmaceutical composition as claimed in claim 1, wherein the composition comprises a mixture of metaxalone and a solubilizing agent.
8. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value between 10 and 40 $\mu$ m in diameter, characterised in that the pharmaceutical composition has enhanced oral bioavailability.

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9. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone has specific surface area per unit volume of more than  $1.5\text{m}^2/\text{cm}^3$ .

10. **(Previously Presented)** A pharmaceutical composition as claimed in claim 9, wherein the metaxalone has specific surface area per unit volume of more than  $2.5\text{m}^2/\text{cm}^3$ .

11. **(Previously Presented)** A pharmaceutical composition as claimed in claim 10, wherein the metaxalone has specific surface area per unit volume of more than  $3.0\text{m}^2/\text{cm}^3$ .

12. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $40\mu\text{m}$ , 90% undersize value of  $30\mu\text{m}$ , and 50% undersize value of  $10\mu\text{m}$ .

13. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $30\mu\text{m}$ , 90% undersize value of  $14\mu\text{m}$ , and 50% undersize value of  $6\mu\text{m}$ .

14. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the metaxalone comprises the following particle size distribution characteristics: 99% undersize value of  $10\mu\text{m}$ , 90% undersize value of  $5\mu\text{m}$ , and 50% undersize value of  $3\mu\text{m}$ .

15. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the amount of metaxalone is in the range of 400mg to 1600mg.

16. **(Previously Presented)** A pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically acceptable excipient comprises a wetting agent.

17. **(Previously Presented)** A pharmaceutical composition as claimed in claim 16, wherein the wetting agent comprises a surfactant.

18. **(Previously Presented)** A pharmaceutical composition as claimed in claim 17, wherein the surfactant comprises sodium lauryl sulfate.

19 - 22        **(Cancelled)**

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23. (Previously Presented) A pharmaceutical composition as claimed in claim 1 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.

24. (Cancelled)

25. (Cancelled)

26. (Cancelled)

27. (Previously Presented) A pharmaceutical composition comprising metaxalone and at least one pharmaceutically acceptable excipient, wherein at least 99% of the metaxalone has a particle size not more than about 10 $\mu$ m in diameter.

28. (Cancelled)